Lake Region Medical

OCT 17 2012

510(k) Summary
as required by 21 CFR 807.92(c)

Device Name	Charter™ Guidewire
Submitters name/contact details	Brivant Ltd, Parkmore West Business Park, Galway, Ireland Contact Details: Kenneth Walsh Senior QA/RA Supervisor Tel: +353 91 385391 Fax: +353 91 766598
Summary Preparation Date	31st August 2012
Device Name & Classification	Trade Name: Charter™ Guidewire Common Name: Guidewire Classification Name: Catheter, Guidewire Device Classification: Class II, 21 CFR §870.1330 Product Code: DQX
Intended Use	Intended Use: The Charter™ Guidewires are intended for use in the coronary and peripheral vasculature. Contraindications: The Charter™ Guidewire is not intended for use in the cerebral vasculature. Patients judged not acceptable for percutaneous intervention (PCI)
Device Description	The Charter™ Guidewire is a disposable medical device designed for single use only. It consists of a PTFE coated 140cm, 180cm, or 300cm 0.014", 0.016"or 0.018" diameter stainless steel core wire, one end of which is reduced in diameter over a 43cm approx. segment in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness and can be varied to produce various levels of support. The distal part of the reduced section is covered with a 3cm, 0.010" platinum tungsten spring coil. This provides greater visibility on x-ray equipment. A 39cm approx. length of black / grey Estane 88A radiopaque heat shrink polymer tubing is applied over the tapered distal end of the wire and ground to form a constant outer diameter, OD, equivalent in diameter to the main core body. Coatings are placed on the device to improve the lubricity and ease in its advancement through the guide catheter and the blood vessel

Predicate Devices	**Manufacturer**	**510k**	**Date**
	Charter Guidewire	K103377	18th May 2011

Principle of	The Charter™ Guidewire is operated manually by a manual process

Operation	
Comparison of Technological Characteristics	The Charter™ wire has the following differences from the originally approved devices. - Introduction of a 0.016" diameter range. - Introduction of a "soft" version tip providing models with greater distal flexibility. - Introduction of 300cm length models. In vitro bench testing was performed to support a determination of substantial equivalence (refer to performance testing below) between the new Charter™ Guidewires models and the existing. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the existing devices in the range. The introduction of these new models raise no new issues of safety and effectiveness such that the proposed new Charter™ Guidewire models are considered substantially equivalent to the predicate devices.
Performance Testing (non-clinical)	In vitro bench tests were carried out to demonstrate equivalence with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995". The following bench tests were performed: - Tensile Strength - Torque Strength - Outer Diameter measurement - Torque Response - Catheter Compatibility - Coating Adherence/Coating Integrity - Tip Stiffness - Particulate Residue The results from these performance evaluations demonstrated that the Charter™ Guidewire met the acceptance criteria defined in the product specification and performed comparably to the predicate device.
Conclusions	Based on safety and performance testing, technological characteristics and the indications for use for the device, the proposed new Charter™ Guidewire models has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the original

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Brivant Ltd.
Lake Region Medical International Research & Development Centre
c/o Kenneth Walsh
Parkmore West Business Park
Galway
Ireland

Re: K122856
Trade/Device Name: Charter Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX

Dear Mr. Walsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122856

Device Name: **CHARTER™ GUIDEWIRE**

Indications for Use: Charter™ Guidewires are intended for use in the coronary and peripheral vasculature.

Contraindications: The Charter Guidewire is not intended for use in the cerebral vasculature.
Patients judged not acceptable for percutaneous intervention (PCI).

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122856